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APPLICATION NO.	FILING DATE		FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
09/202,464	03/09/99	KINO		K	06501/024001

JANIS K FRASER FISH & RICHARDSON 225 FRANKLIN STREET BOSTON MA 02110-2804 HM12/0309

EXAMINER HUYNH, P

ART UNIT PAPER NUMBER

DATE MAILED: 03/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

	Application No.	Applicant(s)					
Office Action Summary	09/202,464	KINO ET AL.					
Onice Action Cummary	Examiner	Art Unit					
	" Neon" Phuong Huynh	1644					
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE One MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status							
1) Responsive to communication(s) filed on 06 J	uly 1999 and 09 March 1999 .						
2a) This action is FINAL. 2b) Thi	s action is non-final.						
	3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims							
4)⊠ Claim(s) ' <u>1-3, 5, 7, 11, 13-14, 17-28</u> is/are pending in the application.							
4a) Of the above claim(s) is/are withdrawn from consideration.							
5) Claim(s) is/are allowed.							
6) Claim(s) is/are rejected.	6) Claim(s) is/are rejected.						
7) Claim(s) is/are objected to.	7) Claim(s) is/are objected to.						
8) Claims <u>1-3, 5, 7, 11, 13-14, 17-28</u> are subject	to restriction and/or election requ	uirement.					
Application Papers							
9) The specification is objected to by the Examiner.							
10) The drawing(s) filed on is/are objected to by the Examiner.							
11) The proposed drawing correction filed on is: a) approved b) disapproved.							
12) The oath or declaration is objected to by the Examiner.							
Priority under 35 U.S.C. § 119							
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).							
a) All b) Some * c) None of:							
1. Certified copies of the priority documents have been received.							
2. Certified copies of the priority documents have been received in Application No							
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).							
* See the attached detailed Office action for a list of the certified copies not received.							
14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).							
Attachment(s)							
<ul> <li>15) Notice of References Cited (PTO-892)</li> <li>16) Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>17) Information Disclosure Statement(s) (PTO-1449) Paper No(s)</li></ul>	19) Notice of Informal	ry (PTO-413) Paper No(s) Patent Application (PTO-152)					

U.S. Patent and Trademark Office PTO-326 (Rev. 9-00) Application/Control Number: 09/202,464

Art Unit: 1644

## **DETAILED ACTION**

- 1. The location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1644, Group 1640, Technology Center 1600.
- 2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. 1.821(a)(1) and (a)(2). Applicant's compliance with sequence's rule is acknowledged.
- 3. Applicant's preliminary amendments, filed on 03/9/99 and 07/06/99 (Paper No. 5/7), are acknowledged.

Claims 4, 6, 8, 9, 10, 12, 15 and 16 have been canceled.

Claims 11-16, 17-28 have been added.

Claims 1-3, 5, 7, 11, 13-14, 17-28 are pending in instant application.

## Election/Restrictions

4. Restriction to one of the following inventions is required under 35 U.S.C. 121 and 372.

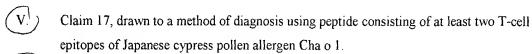
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this Action, to elect a single invention to which the claims must be restricted:

- Claims 1, 3 and 5, drawn to a peptide, a composition comprising at least two T-cell epitopes of Japanese cypress pollen allergen Cha o 1.
  - II. Claims 2, 11 and 13, drawn to a peptide, a composition comprising at least two T-cell epitopes of Japanese cypress pollen allergen Cha o 2.
- Claim 7, drawn to a method of treating or preventing pollinosis caused by tree pollens in springtime, comprising administering the peptide consisting of at least two T-cell epitopes of Japanese cypress pollen allergen Cha o 1.
  - IV. Claim 14, drawn to a method of treating or preventing pollinosis caused by tree pollens in springtime, comprising administering the peptide consisting of at least two T-cell epitopes of Japanese cypress pollen allergen Cha o 2.

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VI. Claims 18-19, drawn to an analog of peptide consisting of at least two T-cell epitopes of Japanese cypress pollen allergen Cha o 1 by amino acid substitution wherein the analog peptide stimulates T cell response to the wild-type peptide.

VII. Claim 20, drawn to a process of making an analog peptide consisting of at least two T-cell épitopes of Japanese cypress pollen allergen Cha o 1 by amino acid substitution.

VIII. Claim 21, drawn to a method of diagnosis using peptide consisting of at least two T-cell epitopes of Japanese cypress pollen allergen Cha o 2.

IX. Claims 22-23, drawn to an analog of peptide consisting of at least two T-cell epitopes of Japanese cypress pollen allergen Cha o 2 by amino acid substitution.

Claim 24, drawn to a process of making an analog peptide consisting of at least two T-cell epitopes of Japanese cypress pollen allergen Cha o 1 by amino acid substitution.

(XI.) Claims 25-26, drawn to a modified peptide consisting of at least two T-cell epitopes of Japanese cypress pollen allergen Cha o 1 by addition or deletion of one or more amino acid residues.

XII. Claims 27-28, drawn to a modified peptide consisting of at least two T-cell epitopes of Japanese cypress pollen allergen Cha o 2 by addition or deletion of one or more amino acid residues.

The inventions listed as Groups I-XII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The Invention of Group VI-X was to have no special technical feature that defined the contribution over the prior art of Ikagawa *et al.* (J Allergy Clin Immunol 97(1 pt 1): 53-64, Jan 1996).

Ikagawa *et al.* teaches how to make analogs of Japanese cedar pollen (Cry j1) carrying the T cell epitope by amino acid substitution (See entire document). Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have single general inventive concept and lack unity of invention.

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5. Irrespective of whichever group applicant may elect, applicant is further required under 35 U.S.C. 121:

To elect a specific T cell epitopes identified by SEQ ID NOS as recited in claim 1 if Group I, III, V, VI, VII, X, XI is elected.

To elect a specific T cell epitopes identified by SEQ ID NOS as recited in claim 2 if Group II, IV, VIII, IX, or XII is elected.

These species are distinct because the different compounds, which differ with respect to their structure and biochemical properties, to prevent or treat pollinosis. Therefore, they are patentably distinct.

- 6. Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 2 are generic.
- 7. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

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9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

- 10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 8:00 am to 5:00 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.
- Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phuong N. Huynh, Ph.D.

Patent Examiner

Technology Center 1600

March 7, 2001

Patrick J. Nolan, Ph.D.

Patrick & Nolan

**Primary Examiner** 

Technology Center 1600